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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,032	03/14/2002	Bruce H Dewoolfson	01891.0015	6642
22852	7590	08/11/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,032	DEWOOLFSON ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 1 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3-14-02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 1-29 are pending.

Applicants' request (filed 18 June 2004) for extension of time of two months has been entered.

Election/restriction

Applicants' election with traverse of Group I, claims 1-10 is acknowledged. The traversal is on the ground(s) that the claims of Groups I-IV should be examined together as examination of the Groups does not result in a serious burden to Examiner (see page 3); and that the subject matter which the applicants regard as their invention should not be restricted (see page 4). The Applicant's traversal has been fully considered but not persuasive.

It is of note that the current application is a 371 of PCT/US00/25190 application. In order for the subject matter to be considered as an invention, the instant application must show holding unity. However, as indicated in the Office action mailed 18 March 2004, the instant claims do not have common technical feature (inserting orthokeratological lens to the subject) since prior to effective filing date of the instant application, Harris *et al.* teach a method of reshaping corneal curvature comprising providing a contact lens to a patient and applying agent to patient eye, wherein the agent acts for accelerated reshaping of the corneal tissue and making cornea more pliable, which teach the subject matter set forth in the instant claim 25. In addition, the step of inserting an orthokeratological lens into a patient's eyes is absent (not required) in the Group I; and thus, Group I and Group IV are directed to patentably distinct processes. Also, Group IV method comprises use of the orthokeratological lens whereas the method of Group I or Group III

Art Unit: 1653

does not require the said lens. Thus, the claimed composition does not constitute a special technical feature linking all claims, as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

Considering the issue as to if there is a serious burden to Examiner, the applicants' argument is found unpersuasive because each types of FACIT (see the instant claim 6) are patentably distinct from one another, and because *any combination* of four types of FACIT compositions encompassing at least six possibilities *plus* the four distinct/different individual compositions would result in a burden to the Examiner. The requirement (including "additional election" requirement) is therefore still deemed proper and is therefore made FINAL.

Claims 11-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Therefore, elected claims 1-10 together with the elected Type VI FACIT and decorin are under examination to the extent that they are drawn to the elected invention.

IDS

The references listed in IDS filed 14 March 2002 have been considered by Examiner.

Object to Declaration

The oath or declaration of this application is defective because Inventor Bruce H. DeWoolfson appears to not indicate whether or not he is US citizen (se page 1 of the Declaration)

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

Art Unit: 1653

(1) The abstract of the disclosure is objected to because the abstract should be in a single paragraph on a separate sheet within the range of 50 to 150 words. Note that the current application does not contain a abstract in a separate sheet.

(2) In page 9, line 2, "NC3" should be spelled out in full for the first instance of use, e.g., "noncollagenous domain 3 (NC3)". Also, see page 10, line 4 from the bottom, "BM"; page 12, line 7, "TGF β ", line 10, "GAG", line 11, " β FGF", and line 7 from the bottom, "EGF"; and page 22, line 8 from the bottom, "TEM".

In claim 1, "a" before "administering to ..." should be deleted because since has only one step been claimed. See also claim 9.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "stabilizing agent from a collage ..."; "from" of the recitation renders claim 1 indefinite because it is unclear that whether or not the said stabilizing agent is made from, or formulated from, or chosen from said collagen composition. See also claim 9. In addition, claim 1 recites "chosen from ..."; the recitation is indefinite because it is not an acceptable Markush language, and because "chosen from" can result in two or more two components being chosen. The dependent claims are also rejected.

Art Unit: 1653

Claim 2 recite "a patient"; it not clear as to whether or not the said patient is the same as the patient recited in claim 1.

Claim 4 recitation "... a fibril diameter of the cornea" is awkward and not apparent because fibril diameter is not a component of said cornea. Suggest "... diameter of a corneal fibril' instead.

Claim 8 recites the limitation "the concentration". There is no antecedent basis for this limitation in claim 1 from which claim 8 depends.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.
Art Unit 1653, Examiner
July 21, 2004



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER